

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	W. Jean Dodds	Examiner:	Pablo S. Whaley
Serial No.:	10/635,707	Group Art Unit:	1631
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Customer No.:	33717	Confirmation No.:	8325
Title:	SYSTEM FOR ANIMAL HEALTH DIAGNOSIS		

CERTIFICATE OF TRANSMISSION

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Name: Kelly Simpson

**SUPPLEMENTAL DECLARATION OF W. JEAN DODDS
IN SUPPORT OF PATENTABILITY**

I, W Jean Dodds, declare as follows:

1. I have personal knowledge of the matters set forth below and if called as a witness could and would competently testify thereto.
2. I submit this Declaration in support of the patentability of the inventions claimed in the patent applications listed above. These inventive features of the diagnostic testing protocols and the reporting systems are clearly distinguishable from anything else in the field.
3. I have previously made a Declaration relating to issues surrounding these patent applications. In part and as appropriate, I repeat herein some of the statements of that declaration.
4. I am the Applicant in the above application. I am also the inventor and patentee in the cited US Patent 6,287,254 (Dodds Patent) and Dodds (WO/2001/028415).

5. Dodds (WO/2001/028415) does not have icons where:

the characteristics of the ...icons ...[are] such as to be representative of the textual content of the supplementary report, and different selectable icons[are] individually related to animal characteristics of age and animal grouping, andicons for animal characteristics dependant on age and on animal grouping, andicons for groupings of the selected animal groups of adult, puppy-adolescent, geriatric, or large breed dog andicons for a disease state, being thyroid disease, theicons being representative of being normal relative to thyroid disease, or abnormal relative to thyroid disease.

6. I am also the author of the reference of Dog World 1992, (Autoimmune thyroid disease, April 1992) as applied by the Examiner. Dodds (Dog World 1992) does not disclose anything to do with optimal conditions or ranges.

7. I am a recognized expert in the area of veterinary medicine related to diagnostics, particularly of thyroid disease in small animals.

8. I have been involved in the animal health diagnostics for about 40 years and am considered by my peers as a preeminent leader in the field. I am also aware of the different techniques for reporting on animal health based on manual, computer and laboratory data. I have run my own laboratory in different forms for about 30 years. This is a main activity of my current business at www.hemolife.org. Over this time I have provided diagnosis for literally tens of thousands of animal conditions. Before my current invention of the present applications there was no computerized manner of diagnosing and delivering enhanced reports in animal medicine. I attach a copy of my resume as Exhibit A. The technology of the claims of the present applications is directed to an invention which avoids the problems with cumbersome and potentially inaccurate diagnostic reporting of animal health conditions.

9. The claims of the present application represent an important advance scientifically and technically over the technology of the claims of my earlier Dodds Patent 6,287,254, Dodds (WO/2001/028415) and the Dodds 1992 Dog World article.

10. No where prior to the present patent application has there been any suggestion teaching or disclosure of diagnostic systems for reporting enhanced reports in a manner claimed in the present application. Never before has there been recognition of diagnosing thyroid disease for adult animals using the ranges claimed in the present applications.

11. In view of my experience in the field of animal health diagnosis, I believe that the icon system was not an obvious development from the disclosures I made in the prior Dodds Patent, Dodds (WO/2001/028415) or in Dog World 1992.

12. The Dodds Patent, Dodds (WO/2001/028415) and Dog World 1992 simply do not teach, suggest or disclose in any sense a supplemental or enhanced report or a second computer program. Further there is not the remotest teaching or suggestion of an optimal levels as now claimed in the present applications.

13. The Dodds Patent, Dodds (WO/2001/028415) and Dog World 1992 do not disclose, teach or suggest that an alternative embodiment of data interpretation performed by algorithm and outputted to a user via an expert interface can be by additional reports generated using a second program comprising menus and icons or GUIs.

14. The Dodds Patent, Dodds (WO/2001/028415) and Dog World 1992 are not a disclosure, teaching or suggestion of the present invention, and nor would it have been obvious to modify the teachings of my prior disclosures (Dodds Patent, Dodds (WO/2001/028415) and Dog World 1992) or would it have been obvious to try from my knowledge at the time to obtain the features of the present invention.

15. The functional and generated icons representing textual data define an important and patentable advance in the field of animal health diagnosis.

16. I consider that the icon diagnostic reporting systems of the present applications would not have been obvious at the time in the light of my prior animal health diagnosis methods in Dodds Patent, Dodds (WO/2001/028415) and Dog World 1992. It would have taken

ingenuity to achieve the successful animal health diagnosis systems with the invented icon systems.

17. None of prior art as applied by the Examiner discloses teaches, suggests the icons as I propose in my two applications 10/635,707 and 10/932,504. Also there is no disclosure, teaching or suggestion of anything relating to the thyroid normal optimal levels as now claimed.

18. The Dodds Patent (US Patent 6,287,254) and Dodds (WO/2001/028415) are my inventions. They deal with automatic reporting of disease states and the access to the reporting systems. They relate to considering the phenotype and the genotype data to enhance the diagnostic analysis. They do not teach the thyroid optimal values as now claimed.

19. Dodds (Dog World 1992) relates to thyroid disease conditions in small animals generally. It does not teach the thyroid optimal levels as now claimed.

20. There is no relevant experimental data comparing the closest prior art systems of the different Dodds systems, namely the Dodds Patent, Dodds (WO/2001/028415) and Dog World 1992. The icon use in Dodds Patent, and Dodds (WO/2001/028415) has nothing remotely to do with icons as used in the present applications 10/635,707 and 10/932,504. It is not possible to show different comparative experimental data because the technologies and reagents are so different that it is illogical to try to do so.

21. The prior art systems are without selectable icons, an indeed the ones illustrated in the Figures of Dodds (WO/2001/028415) don't remotely show anything that has:

the characteristics of the ...icons ...[are] such as to be representative of the textual content of the supplementary report, and different selectable icons[are] individually related to animal characteristics of age and animal grouping, andicons for animal characteristics dependant on age and on animal grouping, andicons for groupings of the selected animal groups of adult, puppy-adolescent, geriatric, or large breed dog andicons for a disease state, being thyroid disease, theicons being representative of being normal relative to thyroid disease, or abnormal relative to thyroid disease.

22. Filteau (US 2002/0188896) is not related to animal health and has nothing to do with thyroid disease. Moreover, Filteau does not use a system which deals with a clinical pathologist's pre-diagnosis of animal health, and thereafter the refinement of that pre diagnosis by using the icons to develop the report. Namely, there is no reporting of the analysis through a network to the clinical pathologist wherein the clinical pathologist has the patient record containing the laboratory results and the data relating to the physical characteristics and family and breed history, and such that the clinical pathologist then makes a preliminary diagnosis of the animal health before using the icons.

23. As has been stated above therefore it is clear that the Filteau icons are not remotely selectable icons used in the sense as claimed in the present invention.

24. No where does any prior art teach, disclose or suggest establishing for thyroid disease analysis optimal levels, the levels being defined by a range different to a laboratory reference range as presented in the laboratory report, there being at least one category of the adequate optimal levels, therapeutic response optimal levels, the minimal expectations optimal levels; or the optimal levels for confirming autoimmune thyroiditis.

25. No where does any prior art teach, disclose or suggest:

a. establishing for thyroid disease analysis at least one category of the adequate optimal levels, therapeutic response optimal levels, the minimal expectations optimal levels; or the optimal levels for confirming autoimmune thyroiditis;

b. assessing thyroid function as part of the preliminary analysis by determining the correct category, and

c. an analysis based on the laboratory report as applied to the correct category to thereby obtain a supplemental report

26. No where before the present patent applications did any veterinary diagnostic system use the optimal levels in each of four categories, namely the adequate optimal levels, the

therapeutic response optimal levels, the minimal expectations optimal levels; or the optimal levels for confirming autoimmune thyroiditis. These categories were determined by me by collecting and analyzing data for about 10 years prior to 2002. This analysis and data and categorization were my confidential scientific work and were never published or used until a couple of months before I filed the provisional patent application 60/403,203 on August 12, 2002.

27. It is a major difference in concept, design, degree and kind when considering the obstacles and challenges necessary to provide an effective user friendly reporting system and a thyroid evaluation of optimal characteristics, compared to a general computer driven report non customized to individual cases and not giving any analysis in relation to optimal results. Other persons skilled in the art did not arrive at my solution and invention.

28. At about the time of my Dog World 1992 article I began to collect and analyze scientific data relating to the criticality of applying for the assessment of thyroid function for optimal levels. I have been collecting clinical research data on the optimal levels for thyroid hormones in adult animals and in animals of other ages. In particular, the critical analytes in assessing thyroid function include T4, free T4 and free T3 and the thyroid autoantibodies (T3AA, T4AA). This data has been accumulated covering literally thousands of different animals.

29. By about mid 2002 I had determined that this unpublished data provided not only the best methodology for measuring the analytes of the complete thyroid profile but also identified the optimal ranges for normal and hypothyroid dogs as determined by breed, type and age, and for the optimal levels for the four categories described above. These data were my internal confidential working initial and development documents.

30. The conclusions from these data are that the criteria for the limit applied specifically to adult optimal levels of FT3 is less than 8 pg/mL and of FT4 is less than 3 ng/dL

31. Before the present inventions these data for these optimal levels were never used. Later I began to apply these results for the assessment of thyroid function for adult optimal levels with the criteria of FT3 being less than 8 pg/mL and of FT4 being less than 3 ng/dL.

32. In the context of the relevant art, namely the veterinary diagnostic art, and specifically related to thyroid disease, there are not a small number of limited options which could have been chosen or selected by a skilled practitioner. Indeed, there were several unpredictable alternatives to determine the exact route for successful systems and analyses as claimed in the applications. It would only be with hindsight to discount the number and complexity of the alternatives. My icon diagnostic system and the thyroid ranges have proved superior to anything previously known or used.

33. I went against the conventional wisdom with my analysis and provided systems which are unique in several different ways as defined. I approached the analysis and problem by considering alternative ways to overcome the cumbersome reporting systems, and analysis of the thyroid data. There was an almost limitless array of variables, and the ranges were broad. It would not have been possible to discover workable and optimal conditions which were functionally effective by routine experimentation without some incentive or suggestion to try a specific range or a combination of variables. I do not believe anyone did this before me.

34. The results were unexpected because the set of variables in the combination that I sought was impossible to realize in the diagnostic systems of the prior art. Indeed all the technical literature led me to believe that my goal was impossible to achieve, and that the thyroid analysis should in theory be at a different range. Surprisingly I was able to achieve a degree of reliability of analysis. The combination of features was just the opposite to the prior art and indeed made for a diagnostic systems for thyroid disease which is superior to prior thyroid diagnostic and reporting systems.

35. As example, the major other veterinary animal laboratories in the North America use different criteria for FT3 and FT4

Michigan State University FT3 is less than 12 pmol/L and FT4 is less than 26 pmol/L.

Idexx of Canada FT3 is not measured. FT4 is less than 40 pmol/L.

Advanced Veterinary Analysis of California FT3 is not measured. FT4 is less than 3.10 ng/dL.

Phoenix Central Laboratory FT3 is not measured. FT4 is less than 3.1 ng/dL.

36. Antech Diagnostics is the major veterinary diagnostic laboratory in North America, conducting several thousand thyroid tests per day nationwide. I have consulted for them for many years. Antech, following my expertise, adopted my criteria of FT3 and FT4.

37. I believe that I went contrary to all conventional teachings in achieving this innovative and unique combination of features to have systems as functioning and as claimed in the present application. I believe that I went completely against normal theory in many senses. With regard to the thyroid diagnostic and reporting systems as claimed and the interactions as defined above. Unexpectedly I proved just the opposite of any known theory or implementation of .thyroid diagnostic and reporting systems.

38. The results are more than a mere difference in properties of prior art. The unexpected result is that the new properties differ so as to have been really unexpected. The ability to operate a thyroid diagnostic and reporting as claimed is in a range of operation so different to prior art that it demonstrates a marked improvement of anything before it, and can be classified as "a difference in kind". The unexpected advantageous properties have a major superiority in property of anything that has existed before in the thyroid diagnostic and reporting field.

39. The veterinary diagnostic method which is the subject of these applications have been commercially successful for Hemopet, the Assignee of the technology under the Patent Application Nos. 10/635,707 and 10/932,504. I consider that the commercial success has been

due at least in part to the inventive features of the diagnostic testing protocols and the reporting systems. It is also due to the thyroid diagnosis criteria as claimed in the present applications.

40. I am the President of Hemopet, ("Hemopet") which is the Assignee of the patent application Nos. 10/635,707 and 10/932,504. Hemopet performs thyroid diagnostic and reporting in accordance with the invention. The thyroid diagnostic and reporting system which is the subject of these applications has been commercially successful. I consider that the commercial success has been due in large part to the inventive features of the thyroid diagnostic and reporting systems of the invention. These features distinguish the thyroid diagnostic and reporting from anything else in the category of thyroid diagnostic and reporting.

41. For many years, Hemopet has been engaged in the business of setting up, and developing thyroid diagnostic and reporting test results. The Hemopet results have been available and offered in the United States and throughout the world.

42. One of Hemopet's most successful services is the thyroid diagnostic and reporting systems as claimed in the present applications. Hemopet now uses the thyroid diagnostic and reporting systems according to the invention. The Hemopet thyroid diagnostic and reporting systems are available to veterinarians and pet owners in the United States and around the world. The Hemopet thyroid diagnostic and reporting systems are considered the most comprehensive and accurate thyroid diagnostic and reporting systems, ahead of anything else provide by other providers of thyroid diagnostic and reporting systems. Hemopet has performed since at least about 2005 about \$1,000,000 per annum worth of tests with the invention. This figure has continues to grow at about 10 percent per annum. This involves diagnosing and reporting according to the invention of about an average of 50-75 cases per day.

43. Competitor testing does not provide the reporting enhancements, and the diagnosis using the optimal range, and are cheaper in the market place. There has been no advertising of the testing, and as such this commercial success did not come through extensive advertising of the testing. Despite this the invention is commercial successful based on the very fact of the invention as defined in the claims as now submitted has earned an invaluable

reputation for creating a testing protocol and reporting system that sets the industry standards for accuracy, quality and value. This testing is a worldwide success and continues to be sought from Hemopet from several countries of the world.

44. There are many accolades that Hemopet has received for its thyroid diagnostic and reporting systems. This includes a commitment in 2007 by the New Zealand Kennel Club to endorse and recommend throughout New Zealand that Hemopet be their national testing laboratory. Hemopet is using the invention to diagnose and report results to New Zealand. Also a laboratory in Australia has sought in July 2008 the licensing rights for the technology of the invention.

45. The thyroid diagnostic and reporting systems which are the subject of the present applications operate in a unique manner and these characteristics contribute at least in part to the commercial success of the Hemopet thyroid diagnostic and reporting systems. The commercial success flows from the superior functions and advantages of the thyroid diagnostic and reporting systems as claimed in the pending claims.

All statements made herein of my own knowledge are true, all statements made hereon information and belief are believed to be true, and further these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under U.S.C. 1001, and may jeopardize the validity of the application of any patent issuing thereon.

Dated: August 11, 2008

LA 127,655,846v1



W. JEAN DODDS

Exhibit A

CURRICULUM VITAE OF W. JEAN DODDS

Born Shanghai, China, January 4, 1941

Education

1964 D.V.M. (With honors and distinction)

Ontario Veterinary College, University of Toronto, Guelph, Ontario, Canada
1965 (Feb.) Postgraduate course in medical genetics, Faculty of Medicine, University of Toronto
1965 (May 25 - June 4) Postgraduate course in biochemistry, pathology, and immunology, Albany Medical College

Employment

1964-1965 Assistant Professor, Department of Physiological Sciences, Ontario Veterinary College, Guelph, Ontario, Canada
1965-1967 Research Scientist, Division of Laboratories and Research, NYS Department of Health, Albany (Health Research, Inc.)
1967-1968 Associate Veterinarian (Hematologist), above address
1968-1969 Senior Research Scientist, above address
1969-1984 Senior Research Scientist III to VIII (NYS appointments)
1977-1983 Research Director, Laboratories for Veterinary Science, above address
1983-1988 Chief, Laboratory of Hematology, above address
1988-1992 Director, Comparative Hematology Laboratory, above address (half-time)
1986-present Founder and President, Hemopet, Santa Monica, CA

Membership on Study Sections, Editorial and Advisory Boards; Other Consultantships

1974-1978 Member, Animal Resources Advisory Committee, Division of Research Resources, National Institutes of Health.
1979-1983 Member, Hematology Study Section, Division of Research Grants, National Institutes of Health.
1982-2000 Hematology Consultant; Canine Practice, Feline Practice, Equine Practice.
1987-1995 Editorial Board, Veterinary Clinical Pathology.
1979-1980 Associate Editor, Laboratory Animal Science.
1970-present Referee for J Amer Vet Med Assoc; Am J Vet Res; J Am Anim Hosp Assoc; Blood; J Lab Clin Med; Brit J Haematol; Thromb Haemost; Thromb Res; Nat Sci Found; Amer Heart Assoc; Can Vet J; Can J Comp Med; Lab Anim Sci.
1972-1974 Member, Executive Committee, Council on Thrombosis, American Heart Association.
1981-1984 Member, Pathology Research Study Committee, American Heart Association
1983-1988 Executive Secretary, NYS Council on Human Blood and Transfusion Services, and NYS Hemophilia Advisory Panel.
1983-1985 Member, Office of Technology Assessment Panel on Alternatives to Animal Use in Testing and Experimentation, U.S. Congress.

- 1973-1978 Member, Subcommittee on Vertebrates, Genetics Society of America.
 1973-1975 Member, Committee on Animal Models and Genetic Stocks, Institute of Laboratory Animal Resources (ILAR), National Research Council-National Academy of Sciences (NRC/NAS).
 1975-1978 Chairman, Committee on Animal Models and Genetic Stocks, ILAR, NRC/NAS
 1974-1976 Chairman, Committee on Animal Models for Thrombosis and Hemorrhagic Diseases, ILAR, NRC/NAS.
 1975-1979 Member, Committee on Veterinary Medical Sciences, Assembly of Life Sciences, NRC/NAS.
 1980-1984 Chairman, Committee on Veterinary Medical Sciences, Assembly of Life Sciences, NRC/NAS.
 1975-1980 Vice-Chairman and Member, Executive Committee and Advisory Council, ILAR, NRC/NAS.
 1974-1983 Chairman, Subcommittee on Animal Models, International Committee on Thrombosis and Haemostasis.
 1976-1978 Member, Committee on Education, ILAR, NRC/NAS.
 1978-1979 Chairman, Special ILAR Evaluation Panel for the Laboratory Animal Data Bank of National Library of Medicine, NRC/NAS.
 1979-1983 Member and Vice-President, Board of Trustees, Scientist's Center for Animal Welfare, Washington, D.C.
 1984-1988 President, Scientist's Center for Animal Welfare, Washington, D.C.
 1984-1987 Member, Scientific Advisory Board, Otisville Biotech, Inc./Alliance Pharmaceuticals, San Diego, CA.
 1986-present Consultant (pro-bono), Veterinary Reference Laboratories, Animed (1986-1988); Professional Animal Laboratory (1990-1994), became Antech Diagnostics, Irvine, CA.
 1986-present President, Hemopet/Pet Life-Line, Santa Monica and Irvine, CA. Nonprofit national animal blood bank program.
 1993-2002 Editor, Advances in Veterinary Science and Comparative Medicine, Academic Press, San Diego, CA.
 2004-2005 Member, Committee on National Needs for Research in Veterinary Medicine, NRC/NAS.

Other Appointments

- 1968-1979 Consultant Veterinarian, Veteran's Administration Medical Center, Albany, NY.
 1970-1979 Adjunct Associate Professor of Medicine, Albany Medical College, Albany, NY.
 1978-2000 Adjunct Associate Professor of Medicine, University of Pennsylvania School of Veterinary Medicine, Philadelphia, PA.
 1979-1990 Adjunct Professor of Pathology, NYS College of Veterinary Medicine, Cornell University, Ithaca, NY.
 1980-1990 Adjunct Professor, Department of Physiology, Albany Medical College.
 1980-1990 Adjunct Professor, Department of Medicine, Albany Medical College.
 1981-1990 Adjunct Professor of Pathology, Albany Veteran's Administration Medical Center.
 1980-1990 Visiting Lecturer, Tuft's University School of Veterinary Medicine, Boston, MA.
 1983-1992 Adjunct Professor, Department of Biological Sciences, State University of New York at Albany (SUNYA).
 1983-1988 Acting Associate Chairman, Department of Laboratory Medicine, Graduate School of Public Health Sciences, SUNYA.

- 1983-1990 Adjunct Professor, Department of Pathology, Albany Medical College.
- 1987-1992 Member, Veterinary Advisory Committee, Biopure Corporation, Boston, MA.
- 1991-1992 Veterinary Consultant, Cryopharm, Pasadena, CA.
- 1991-1998 President, Association of Veterinary Transfusion Medicine.
- 1998-2001 Newsletter Editor, Association of Veterinary Hematology and Transfusion Medicine

Teaching Experience

- 1968-present Continuing medical education credit courses in hematology, immunology and endocrinology for veterinarians and veterinary technologists locally, nationally and internationally.
- 1975-1985 Continuing medical education credit courses and seminars in hematology for physicians and medical technologists, Department of Medicine, Albany Medical College, Union University; Veteran's Administration Medical Center; and Northeastern Region of American Red Cross, Albany, NY.
- 1976-1980 Program Director, NIH/NRSA Postdoctoral research training grant in comparative hemostasis. Four (4) postdoctoral trainees were trained.
- 1978-1985 Annual undergraduate courses in hematology for veterinary students at NYS College of Veterinary Medicine, Cornell University, Ithaca, NY; and Tufts University School of Veterinary Medicine, Boston, MA.
- 1978-2000 Annual undergraduate veterinary student courses at University of Pennsylvania School of Veterinary Medicine, Philadelphia, PA.
- 1993-1999 Veterinary Consultant, Baxter Edwards CVS Division, Irvine, CA.

Honors and Awards

- 1974 Woman Veterinarian of the Year, Women's Veterinary Medical Association, Denver, Co.
- 1977 Region I Award for Outstanding Service to the Veterinary Profession, American Animal Hospital Association, Cherry Hill, NJ.
- 1978 Award of Merit in Recognition of Special Contributions to the Veterinary Profession, American Animal Hospital Association, Salt Lake City, UT.
- 1978 Gaines Fido Award, Dogdom's Woman of the Year, Gaines Research Center, New York, NY and 1990
- 1979 Anstamm Achievement Award, in memory of Senator Anthony Stamm (MI), Scottish Terrier Club of America.
- 1979 Commendation for Service, Albany Veteran's Administration Medical Center.
- 1984 Centennial Medal Award, University of Pennsylvania School of Veterinary Medicine.
- 1987 Elected Distinguished Practitioner, National Academy of Practice in Veterinary Medicine.
- 1994 Holistic Veterinarian of The Year, American Holistic Veterinary Medical Association.
- 2004 Veterinarian of the Year, All-Saints Blessings for the Animals

Professional Societies

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| American Veterinary Medical Association | American Society of Hematology |
| Canadian Veterinary Medical Association | American Association of Pathologists |
| Ontario Veterinary Medical Association | American Heart Association |
| American Society of Veterinary Clinical Pathologists | American Association of Blood Banks |

Areas of Expertise

Comparative thrombosis and hemostasis
Animal models
Comparative immunohematology and endocrinology
Laboratory animal medicine; animal welfare

Patents

U.S. Patent 5,196,311	ELISA Test for von Willebrand Factor
U.S. Patent 5,202,264	ELISA Using Multi-Species Antibodies for Detection of von Willebrand Factor in Multiple Species
U.S. Patent 5,486,685	Oven with Food Presence Indicator
U.S. Patent 5,830,709	Detection Method for Homologous Portions of a Class of Substances
U.S. Patent 6,287,254	Animal Health Diagnostics
U.S. Patent 6,730,023	Animal Genetic and Health Profile Database Management
U.S. Patent 9,419,192	Animal Genetic and Health Profile Database Management
U.S. Patent 9,898,193	Animal Health Care, Well-Being and Nutrition
U.S. Patent 7,029,441	Animal Health Care, Well-Being and Nutrition

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